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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,266	03/09/2001	Arthur A. Alfaro	285-148	7075

7590

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Peter Dilworth  
Dilworth & Barrese  
333 Earle Ovington Blvd.  
Uniondale, NY 11553

EXAMINER

PRIDDY, MICHAEL B

ART UNIT

PAPER NUMBER

3732

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/803,266

Applicant(s)

ALFARO ET AL.

Examiner

Michael B Priddy

Art Unit

3732

*Handwritten signature*

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED- (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3-17, 19-21 and 23-37 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 18 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

Claims 1, 2, 18 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferree (US 6,432,107) in view of Anderson et al. (US 6,458,158). Ferree teaches an enhanced area spinal fusion device comprising a first, substantially closed C-shaped ring component, consisting of elements 440 and 446, which has upper and lower vertebral engaging surfaces and a thickness between these upper and lower surfaces; and a second component 420 engagable within the first component 440 & 446 and having a height greater than the thickness of the first component 440 & 446. Fig. 4D illustrates the intended implantation of the device of Ferree into the vertebra of a patient. From this figure it is clear that, upon implantation, the ring 440 & 446 would be positioned within an excised disk space between adjacent vertebrae; and the locking implant 420 would be engaged within the ring 440 & 446 (via screws 444) and with the adjacent vertebrae. The method set forth in claim 18 is therefore considered inherent. Hence Ferree teaches all of the limitations of the present invention except that the first and second components are comprised of bone; and that the first component is generally ring-shaped.

Anderson et al. teach a composite bone graft one embodiment of which (as depicted in Figs. 14A-14C) is a cervical wedge for use in cervical fusions comprising first and second cortical bone portions 82 held together by two cortical bone pins 7. Anderson discloses in lines 28-32 of column 1, that "the composite bone graft promotes

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the growth of patient bone at an implantation site by promoting osteoinductivity and cellularization". It would have been obvious to one of ordinary skill in the art at the time of the present invention to form the fusion device of Ferree of composite bone so as to "promote the growth of patient bone at an implantation site".

Concerning the shape limitation, "generally ring-shaped", it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the spacer of Ferree of a generally ring-shape, since applicant has not *disclosed* that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a forming edge in the heating portion or clamp. In re Dailey and Eilers, 149 USPQ 47 (1966).

#### ***Allowable Subject Matter***

Claims 3-17, 19-21 and 23-37 are allowed.

#### ***Response to Arguments***

Applicant's arguments filed 05/10/2004 have been fully considered but they are not persuasive. With respect to claim 1, Applicant has argued that Ferree does not teach a generally ring-shaped first component and asserts "the ring shape of Applicant's spacer component is essential to the proper functioning of the claimed two-part intervertebral spacer in the claimed method of restoring spacing between adjacent vertebrae since it better conforms to the anatomy of the intervertebral space than, say,

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a rectangular shape, the latter being fairly descriptive of the overall configuration of the conjoined elements 440 and 446 of Ferree Fig. 4." While the Examiner may agree with Applicant that it seems a ring-shaped spacer component would conform better than other shapes to the anatomy of the intervertebral space, this "criticality" was not disclosed in the application as originally filed and therefore amounts to a matter of opinion.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael B. Priddy whose telephone number is (703) 308-8620. The examiner can normally be reached on Mon.-Fri. 8 a.m. - 5 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (703) 308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

Michael B. Priddy

*Michael B. Priddy*  
August 13, 2004

*Kevin Shaver*  
KEVIN SHAVER  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700